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(Original Signature of Member)

107TH CONGRESS
2D SESSION

H. R. _____

To restore standards to protect the privacy of individually identifiable health information that were weakened by the August 2002 modifications, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. MARKEY introduced the following bill; which was referred to the Committee on _____

A BILL

To restore standards to protect the privacy of individually identifiable health information that were weakened by the August 2002 modifications, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Stop Taking Our Health Privacy (STOHP) Act of 2002''.

SEC. 2. FINDINGS.

The Congress finds as follows:

(1) People in the United States are deeply concerned about the confidentiality of their health information. According to a recent survey conducted by the Princeton Survey Research Associates, 1 in 6 people in the United States has done something out of the ordinary to keep personal health information confidential, including withholding information, providing inaccurate information, or, in some cases, avoiding care entirely.

(2) Pursuant to the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 1936 et seq.) (commonly referred to as ''HIPAA''), the Clinton Administration issued comprehensive medical privacy regulations which were promulgated in final form in December 2000.

(3) Such regulations established a sound foundation of privacy protections by prohibiting the use or disclosure of an individual's health information unless specifically authorized by the regulations or by the individual. The regulations also provided individuals with the right to be notified of the privacy practices of health plans, health care providers, and health care clearinghouses regarding disclosure of

their health information, the right to access and copy their own health records, and the right to request corrections of their health records, among other provisions.

(4) Such regulations took effect in April 2001 and require health care providers, health plans (other than small health plans) and health care clearinghouses to comply not later than April 2003.

(5) In August 2002, the Bush Administration issued a final rule that significantly weakened medical privacy protections in the December 2000 medical privacy rule.

(6) The Bush Administration undermined medical privacy protections by eliminating the rule's requirement that covered entities obtain patient consent before using and disclosing patient health information for treatment, payment, and health care operations. This change means that patients' medical records can be used and disclosed without their permission for a wide range of purposes including business activities that have nothing to do with the treatment of a patient, such as the sale or merger of a health maintenance organization. This change also allows the use and disclosure of information in existing medical records even though patients dis-

closed the information with the understanding and expectation that it would not be further used or disclosed without their consent. The elimination of consent compromises the confidentiality at the heart of physician-patient relationships, which is indispensable for the delivery of high-quality, thorough care.

(7) The Bush Administration also undermined medical privacy protections by expanding the circumstances under which patients' information can be shared without their knowledge or consent to include activities that consumers typically consider marketing. This change was accomplished by narrowing the scope of activities that are regulated by the provisions of the rule governing marketing. Under this change, pharmacies and other providers can use a consumer's medical information without consent to mail the consumer unsolicited drug product recommendations, without having to disclose fees paid by drug companies for sending such communications or provide the consumer an opportunity to decline to receive such communications in the future.

(8) The Bush Administration further undermined medical privacy protections by changing the language in the section of the rule governing public health to allow the disclosure of medical information

without patient permission to entities regulated by the Food and Drug Administration, such as pharmaceutical companies and medical device manufacturers, for an expanded and broad range of purposes which may include marketing campaigns. In contrast, the December 2000 rule allowed nonconsensual disclosure of patient health information for an exclusive list of public health related activities, such as for the purpose of reporting serious side effects from a prescription drug to the Food and Drug Administration.

(9) Reversal of the Bush Administration's changes to the December 2000 medical privacy rule is integral to any effort to ensure medical privacy protection for consumers and preserve access to high-quality health care in the United States.

(10) Core medical privacy protections of the December 2000 medical privacy rule should be restored by—

(A) reinstating the patient consent requirement for treatment, payment, and health care operations, while ensuring that the requirement does not impede important health care activities such as filling pharmaceutical prescriptions and making referrals;

(B) returning to the December 2000 definition of ''marketing'' and thus ensuring that activities typically considered marketing, such as drug companies paying pharmacies to send product recommendations to patients, fall under the rule's privacy protections relating to the use of patient health information for marketing activities; and

(C) eliminating the broad ''public health'' exemption created by the August 2002 rule.

SEC. 3. PURPOSE.

The purpose of this Act is to restore patient privacy protections essential for high-quality health care that were undermined by the Bush Administration's August 2002 modifications of the December 2000 medical privacy rule.

SEC. 4. RESTORATION OF PRIVACY PROTECTIONS.

(a) CONSENT FOR USES OR DISCLOSURES TO CARRY OUT TREATMENT, PAYMENT, OR HEALTH CARE OPERATIONS.—

(1) IN GENERAL.—The modifications made to section 164.506 of title 45, Code of Federal Regulations, by the August 2002 medical privacy rule shall have no force or effect.

(2) CLARIFICATION REGARDING INSTANCES WHEN CONSENT IS NOT REQUIRED.— In addition to

the circumstances described in the December 2000 medical privacy rule, and notwithstanding any provision to the contrary, such section 164.506 shall be construed and applied so as to permit a health care provider to use or disclose an individual's protected health information without obtaining the prior consent of the individual in the following circumstances:

(A) A health care provider may use or disclose an individual's protected health information to fill or dispense a prescription, search for drug interactions related to that prescription, and determine eligibility and obtain authorization for payment regarding that prescription, if the health care provider obtains written consent from the individual as soon as practicable.

(B) A health care provider may use or disclose an individual's protected health information to carry out treatment of that individual if—

(i) the individual and the health care provider have not had in-person communication regarding such treatment;

(ii) obtaining consent would be impracticable;

(iii) the health care provider determines, in the exercise of professional judgment, that the individual's consent is clearly inferred from the circumstances, such as an order or referral from another health care provider; and

(iv) the health care provider obtains written consent from the individual as soon as practicable.

(b) MARKETING.—

(1) IN GENERAL.—The modifications made by the August 2002 medical privacy rule to the definition of the term ''marketing'' in section 164.501 of title 45, Code of Federal Regulations, shall have no force or effect.

(2) TREATMENT OF CERTAIN COMMUNICATIONS.—The exception for oral communications in paragraph (2)(i) of the definition of the term ''marketing'' in section 164.501 of title 45, Code of Federal Regulations, as contained in the December 2000 medical privacy rule, shall have no force or effect.

(3) AUTHORIZATIONS FOR MARKETING.—Section 164.508 of title 45, Code of Federal Regulations, shall be construed and applied so as to require that, if an authorization is required for a use or dis-

closure for marketing, the authorization shall be considered invalid unless it—

(A) uses the term ''marketing'';

(B) states that the purpose of the use or disclosure involved is marketing;

(C) describes the specific marketing uses and disclosures authorized, including whether the protected health information involved—

(i) may be used for purposes internal to the covered entity;

(ii) may be disclosed to, and used by, a business associate of the covered entity; and

(iii) may be disclosed to, and used by, any person or entity other than a business associate of the covered entity; and

(D) states that the use or disclosure of protected health information for marketing will directly result in remuneration to the covered entity from a third party, in any case in which a covered entity expects, or reasonably should expect, that such remuneration will occur.

(c) PUBLIC HEALTH.—The modifications made to section 164.512(b)(1)(iii) of title 45, Code of Federal Reg-

ulations, by the August 2002 medical privacy rule shall have no force or effect.

SEC. 5. DEFINITIONS; EFFECTIVE DATE.

(a) IN GENERAL.—For purposes of this Act:

(1) DECEMBER 2000 MEDICAL PRIVACY RULE.—The term ''December 2000 medical privacy rule'' means the final rule on standards for privacy of individually identifiable health information published on December 28, 2000, in the Federal Register (65 Fed. Reg. 82462), including the provisions of title 45, Code of Federal Regulations, revised or added by such rule.

(2) AUGUST 2002 MEDICAL PRIVACY RULE.—The term ''August 2002 medical privacy rule'' means the final rule, published on August 14, 2002, in the Federal Register (67 Fed. Reg. 53182), that modified the December 2000 medical privacy rule.

(b) OTHER TERMS DEFINED.—For purposes of this Act:

(1) BUSINESS ASSOCIATE; COVERED ENTITY; HEALTH CARE PROVIDER.—The terms ''business associate'', ''covered entity'', and ''health care provider'' shall have the meaning given such terms in section 160.103 of title 45, Code of Federal Regula-

tions, as contained in the December 2000 medical privacy rule.

(2) DISCLOSURE; INDIVIDUAL, PROTECTED HEALTH INFORMATION; TREATMENT; USE.—The terms ''disclosure'', ''individual'', ''protected health information'', ''treatment'', and ''use'' shall have the meaning given such terms in section 164.501 of title 45, Code of Federal Regulations, as contained in the December 2000 medical privacy rule.

(c) EFFECTIVE DATE; NO REGULATIONS REQUIRED.—This Act shall take effect on the date of the enactment of this Act and does not require the issuance of regulations.